IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9148

Bartle, J. September 15, 2013

Lourena M. Boggess ("Ms. Boggess" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In July, 2006, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Charles F. Dahl, M.D., F.A.C.C., F.A.C.P. Based on an echocardiogram dated September 4, 2002, Dr. Dahl attested in Part II of claimant's Green Form that Ms. Boggess suffered from moderate mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® or Redux™.[3]

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2. (...continued)
Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Dr. Dahl also attested that claimant had moderate aortic regurgitation, an abnormal left atrial dimension, New York Heart Association Functional Class III symptoms, and mild or greater
(continued...)

Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of $309,999.[4]

Dr. Dahl also attested in claimant's Green Form that Ms. Boggess did not have echocardiographic evidence of a rheumatic mitral valve (defined as doming of the anterior leaflet and/or anterior motion of the posterior leaflet and/or commissural fusion), except where a Board-Certified Pathologist has examined mitral valve tissue and determined that there was no evidence of rheumatic valve disease. Under the Settlement Agreement, the presence of a rheumatic mitral valve requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)e). As the Trust does not contest claimant's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In November, 2006, the Trust forwarded the claim for review by Zuyue Wang, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Wang concluded that there was no reasonable medical basis for the attesting physician's finding that claimant did not have a rheumatic mitral valve. Dr. Wang

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3. (...continued)
aortic regurgitation confirmed by echocardiogram prior to Pondimin® and/or Redux™ use. These conditions are not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

explained, "There is diastolic doming of [the] anterior mitral valve leaflet, restricted posterior mitral leaflet, [and] fusion of the chordae and commissure."

Based on Dr. Wang's finding that claimant had a rheumatic mitral valve, the Trust issued a post-audit determination that Ms. Boggess was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[5] In contest, claimant argued that her attesting physician had a reasonable medical basis for his assertion that Ms. Boggess did not have a rheumatic mitral valve.[6] In support, Ms. Boggess submitted declarations from Dr. Dahl; Jeffrey S. Osborn, M.D., F.A.C.C.; and Konstantyn Szwajkun, M.D., F.A.C.C. In his declaration, Dr. Dahl stated, in relevant part:

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5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

6. Claimant also contested the Trust's calculation of the amount of her Level III Matrix Benefits. This issue should have been, but was not, raised in an appeal to arbitration. See Audit Rule 18(e). Nevertheless, because her claim was based on her October 5, 2005 valve surgery, the Trust properly calculated the amount of Level III Matrix Benefits due Ms. Boggess. In addition, claimant also argues she should receive additional Matrix Benefits based on an earlier Green Form she submitted. Given our disposition, we need not address this argument.

I have reviewed the tapes of the echocardiograms dated March 11, 2002, September 4, 2002, and September 4, 2003 on Lourena M. Boggess. I will speak specifically of the echocardiogram of September 4, 2002 which was used to do the Green Forms which I filled out on June 12, 2003 and June 23, 2006. Subsequently she had aortic valve replacement and a mitral valve ring on October 5, 2005. Ms. Boggess' echocardiograms do not show rheumatic heart disease. She does not have typical structural changes of, or found with, rheumatic involvement; specifically there is not doming of the anterior mitral leaflet, no anterior motion of the posterior leaflet, nor is there commissural fusion. In addition, there is no calcification of the cords. Doppler examination also shows normal deceleration time with a mitral E-wave. These findings clearly indicate there was no rheumatic mitral valve disease at that time. Nor would rheumatic disease have occurred later. In Dr. Thorne's operative report of October 5, 2005 he describes a mitral valve which had calcification of the anterior commissure but he does not describe rheumatic changes and he does not mention rheumatic heart or valve disease. He does not describe Aschoff bodies. It is of note that the reading cardiologist, Dr. Konstantyn Szwajkun, described the mitral valve as being structurally normal on his report of the echocardiogram done September 4, 2002. In fact, all of his echocardiogram reports find a structurally normal mitral valve.

....

There is no echocardiographic, Doppler, or surgical evidence of rheumatic involvement of the mitral valve....

In his declaration, Dr. Osborn stated, in relevant part:

[I]t is my opinion based on my review of the echocardiographic and documentary evidence provided, as well as my education, experience, familiarity with relevant medical

> literature, and based on reasonable medical certainty, that Lourena M. Boggess did not have evidence of Rheumatic heart disease or Rheumatic heart valve disease of the mitral or aortic valve on her September 4, 2002 echocardiogram, or at any time before or after September 4, 2002. It is my further opinion that the Attesting Physician, Dr. Charles F. Dahl, was correct in finding and attesting on both Green Forms that Ms. Boggess did not have or show evidence of Rheumatic heart disease or Rheumatic heart valve disease of either the mitral or aortic valve on her 9/4/02 echocardiogram or at any time before or after 9/4/02, based on the echocardiogram of 9/4/02, other echocardiograms and [echocardiogram] reports, and the medical, hospital, surgical and pathology records and reports. It is my further opinion that Dr. Dahl had a reasonable medical basis - indeed ample and overwhelming medical bases - for his findings and conclusions regarding the absence of evidence of Rheumatic heart diseases or Rheumatic heart valve disease of the mitral or aortic valve. Again, my opinion is based on my review of Ms. Boggess' 9/4/02 [echocardiogram] on VCR and then in real time on a current Acuson Sequoia 512 ultrasound system, during which the frames were located and findings and measurements made .... My opinion in this regard is also based on all of the echocardiographic tapes and reports and the other documents and records provided, and on my education, experience, training, familiarity with the relevant medical text and literature, and further based on reasonable medical certainty.

Dr. Osborne also attached several still frame images that purportedly demonstrate claimant's echocardiogram did not show evidence of a rheumatic mitral valve.

In his declaration, Dr. Szwajkun stated, in relevant part:

5. ....

> Based on my review of each of the echocardiograms I have ordered on Ms. Boggess from July 27, 1994 through September 6, 2005, there is no evidence of a Rheumatic mitral valve as defined by Question D.10 of the Green Form.

....

7. Dr. Kent Thorne's operative report on the mitral and aortic valve surgery performed on Ms. Boggess states that he observed during surgery that Ms. Boggess' mitral valve leaked because the anterior commissure was calcified. Calcification of the anterior commissure is not the same as "commissural fusion", which is a part of the Green Form definition of a Rheumatic heart valve. Therefore Dr. Thorne's finding does not constitute evidence of a Rheumatic heart valve under the Green Form definition. No commissural fusion was observed and reported by Dr. Thorne. This operative report is included in my medical records and chart pertaining to Ms. Boggess....

8. I ordered, reviewed, and interpreted the September 4, 2002 echocardiogram on Ms. Boggess. This echocardiogram showed moderately severe (3+) mitral regurgitation, moderate aortic insufficiency, a normal structural appearance on both the mitral and aortic valve with no evidence of a Rheumatic heart valve or aortic sclerosis, and mild biatrial enlargement.

In addition to these declarations, claimant also submitted a personal affidavit, in which she stated, in relevant part, "I have never experienced or been diagnosed with any Rheumatic Heart Disease, or a Rheumatic Heart Valve problem, at any time." Claimant also argued that the absence of any reference to rheumatic heart or rheumatic heart valve disease in

the medical records she submitted provides a reasonable medical basis for Dr. Dahl's representation. Finally, claimant contended that the auditing cardiologist failed to apply properly the reasonable medical basis standard set forth in the Settlement Agreement.[7]

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Wang submitted a declaration in which she again concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Boggess did not have a rheumatic mitral valve. Dr. Wang stated, in relevant part:

> I find that Claimant's Contest Materials fail to establish a reasonable medical basis for the Attesting Physician's finding that Claimant does not have M-Mode and 2-D echocardiographic evidence of rheumatic mitral valves, and specifically that there is no reasonable medical basis for Claimant's assertion in Contest that Claimant does not have M-Mode or 2-D echocardiographic evidence of rheumatic mitral valves. At Contest, I reviewed Claimant's echocardiogram of September 4, 2002, and confirm my finding of rheumatic mitral valves. Although Claimant's [echocardiogram] does not show typical changes associated with rheumatic valve disease, this is only because the condition is not very advanced. Because the rheumatic disease is not very advanced, the mitral valve does not appear stenotic, however, the tip of the valve is thickened and there is

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7. Claimant also asserted that the issue of reasonable medical basis should be controlled by Lesley v. Chie, 250 F.3d 47 (1st Cir. 2001) and Gallagher v. Latrobe Brewing Co., 31 F.R.D. 36 (W.D. Pa. 1962). We repeatedly have rejected the Gallagher and Lesley decisions as controlling or persuasive. See, e.g., Mem. in Supp. of PTO No. 6269, at 8-9 (May 17, 2006); Mem. in Supp. of PTO No. 6275, at 9 (May 19, 2006).

> doming on the anterior mitral leaflet, consisted [sic] with rheumatic mitral valves. Because only acute rheumatic valve disease presents with Aschoff bodies, that condition is not detected in the pathology sample. The claimant must have acquired rheumatic valve disease before she [was] exposed to the diet pill. The [echocardiogram] report on July 27, 1994 indicated that claimant had 1+mitral regurgitation and 2+ aortic regurgitation. Although it was also indicated that mitral valves appeared to be normal in structure. However, the same physician (Dr. Konstantyn Szwajkun) interpreted that mitral valves had normal appearance on September 4, 2002 echocardiogram. In general, a normal valve does not cause more than mild mitral regurgitation. In addition, the Operative Report indicates that the anterior commissure was calcified and the surgeon was "able to gather enough leaflet tissue to compensate for this restrictive part of her valve at commissure", which is an indicator of rheumatic valve disease.
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> I also reviewed the still frames submitted at Contest, however, I did not find that these still frames established the absence of rheumatic mitral valves. (Systolic doming must be seen in real time; accordingly, the presence or absence of rheumatic mitral valves cannot be determined from review of a still frame).
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> Accordingly, I affirm my findings at audit, that there is no reasonable medical basis for a finding that Claimant does not have M-Mode and 2-D echocardiographic evidence of rheumatic mitral valves.

The Trust then issued a final post-audit determination, again determining that Ms. Boggess was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See

Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why this claim should be paid. On September 6, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7411 (Sept. 6, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on January 16, 2008. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[8] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a

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8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

reasonable medical basis for the attesting physician's finding that she did not have a rheumatic mitral valve. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Boggess repeats many of the arguments she raised in contest. She also contends that the auditing cardiologist "simply came to her own conclusion," which, according to claimant, "is irrelevant under the Settlement Agreement and is an inadequate substitute for a reasonable medical basis analysis." Thus, according to claimant, the auditing cardiologist improperly applied the reasonable medical basis standard by ignoring the physician declarations submitted by claimant. Finally, claimant notes that Dr. Dahl participated in the Trust's Screening Program.[9]

In response, the Trust argues that claimant failed to establish a reasonable medical basis for her attesting physician's finding that claimant did not have a rheumatic mitral valve. The Trust also contends that the auditing cardiologist

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9. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

properly applied the reasonable medical standard and properly conducted the audit of the claim.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Boggess did not have a rheumatic mitral valve. Specifically, Dr. Vigilante stated, in relevant part, that:

> I reviewed the Claimant's echocardiogram of September 4, 2002.... This was a good quality study with the usual echocardiogram views obtained. I reviewed all images of the mitral valve and mitral apparatus in real-time and I digitized these images and reviewed them in multiple loops. Both mitral leaflets were moderately thickened. There was classic doming of the anterior mitral leaflet seen in the parasternal, apical four chamber, apical two chamber and subcostal views. Significant mitral stenosis was not seen. There was anterior motion of the posterior mitral leaflet noted on M-Mode evaluation of the mitral valve in the parasternal long axis view. In addition, there was increased refractoriness and reflectance of echoes in the posterolateral annulus consistent with mild mitral annular calcification of the posterolateral annulus. There was significant thickening of the mitral chords as well as calcification of the tips of the papillary muscles. The motion of the anterior mitral leaflet had a "hockey stick" appearance. Doming and "hockey stick" appearance of the anterior mitral leaflet were due to commissural fusion. Doming motion of the anterior mitral valve leaflet occurred because of restriction of motion of the tips. The belly of the anterior leaflet was more pliable and moved further out causing this abnormal motion. These echocardiographic findings are classic for rheumatic involvement of the mitral valve and were seen in the parasternal long axis view, apical four chamber view, apical two chamber view and subcostal view.... After analyzing

> the September 4, 2002 echocardiogram, I re-reviewed the Declarations of Dr. Dahl, Dr. Osborn, and Dr. Szwajkun. I reviewed the screen shots provided by Dr. Osborn. Based on my review of the echocardiogram of attestation, it would be impossible for a reasonable echocardiographer to conclude that the mitral valve was not a structurally rheumatic valve.
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> ....
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> ... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question D.10. That is, the echocardiogram of September 4, 2002 shows classic rheumatic involvement of the mitral valve with comments as above. An echocardiographer could not reasonably conclude that rheumatic involvement of the mitral valve was not present on this study even taking into account inter-reader variability.

In response to the Technical Advisor Report, claimant asserts that her claim is a "classic case of inter-reader variability" and, therefore, the court should find that there is a reasonable medical basis for the attesting physician's finding that Ms. Boggess did not have a rheumatic mitral valve.

After reviewing the entire Show Cause Record, we find the claimant's arguments are without merit. As an initial matter, we disagree with claimant that the declarations of Dr. Dahl, Dr. Osborn, and Dr. Szwajkun establish a reasonable medical basis for her claim. The auditing cardiologist and the Technical Advisor each reviewed claimant's September 4, 2002 echocardiogram and determined that it revealed evidence of a

rheumatic mitral valve.[10] Specifically, Dr. Wang concluded "that there is no reasonable medical basis for a finding that Claimant does not have M-Mode and 2-D echocardiographic evidence of rheumatic mitral valves."[11] Similarly, Dr. Vigilante concluded that claimant's "echocardiographic findings are classic for rheumatic involvement of the mitral valve and were seen in the parasternal long axis view, apical four chamber view, apical two chamber view and subcostal view."[12]

We also disagree with claimant that the auditing cardiologist did not apply properly the reasonable medical basis standard under the Settlement Agreement. Dr. Wang's initial certification, as well as her subsequent declaration, set forth in detail the bases for her conclusion that the attesting

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10. Despite arguing that the determination of whether she had a rheumatic mitral valve should be confined to the echocardiogram at issue, claimant attempts to rely on numerous other echocardiograms and other medical records to establish a reasonable medical basis for the attesting physician's finding. As the echocardiogram at issue reveals evidence of a rheumatic mitral valve, we reject claimant's assertion that her other echocardiograms and medical records establish a reasonable medical basis for Dr. Dahl's representation that the September 4, 2002 echocardiogram did not have evidence of rheumatic valve disease.

11. Claimant also takes issue with the auditing cardiologist's statement that claimant's rheumatic valve disease "is not very advanced." As the Settlement Agreement mandates the reduction of a mitral valve claim to Matrix B-1 where there is echocardiographic evidence of rheumatic valve disease, the extent of claimant's rheumatic valve disease is irrelevant.

12. Thus, we reject claimant's argument that there is a reasonable medical basis for her claim simply because her attesting physician, Dr. Dahl, participated in the Trust's Screening Program.

physician's finding of no rheumatic mitral valve lacked a reasonable medical basis. For this same reason, we disagree with claimant's contention that Dr. Wang "simply came to her own conclusion." To the contrary, Dr. Wang specifically concluded that Dr. Dahl's representation lacked a reasonable medical basis.

In addition, we reject claimant's argument that the auditing cardiologist ignored the physician declarations and other materials submitted by claimant during contest. Dr. Wang's declaration specifically states that: "In accordance with the Trust's request, I again reviewed the entirety of Claimant's September 4, 2012 echocardiogram tape, as well as Claimant's Contest Materials." Similarly, claimant's assertion that the auditing cardiologist did not review the still frames of claimant's September 4, 2002 echocardiogram ignores Dr. Wang's declaration. It states: "I also reviewed the still frames submitted at Contest, however, I did not find that these still frames established the absence of rheumatic mitral valves. (Systolic doming must be seen in real time; accordingly, the presence or absence of rheumatic mitral valves cannot be determined from review of a still frame)."[13]

Further, claimant's attempted reliance on other medical records, her own affidavit, and a declaration from her treating

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13. The Technical Advisor also reviewed the declarations submitted by Dr. Dahl, Dr. Osborn, and Dr. Szwajkan and the still-frame images submitted by Dr. Osborn and concluded that they did not demonstrate the absence of a rheumatic mitral valve.

cardiologist to establish she was never diagnosed with rheumatic fever also is misplaced. Nothing in the Settlement Agreement provides that evidence of the reduction factor of a rheumatic mitral valve on a claimant's echocardiogram may be disregarded based on an assertion that the claimant never was diagnosed or treated for rheumatic fever. We previously have held that a claimant cannot meet his or her burden of proving the absence of rheumatic mitral valve by reference to statements from a parent and family physician to the effect that claimant never had rheumatic fever. See, e.g., Mem. in Supp. of PTO No. 7466, at 10 (Oct. 10, 2007). As stated in the Settlement Agreement, the only means by which a claimant may rebut echocardiographic evidence of rheumatic valve disease is the specific determination of a Board-Certified Pathologist. Settlement Agreement § IV.B.2.d.(2)(c)ii)e). Claimant has not provided such a determination in this case.

Finally, to the extent claimant argues that inter-reader variability accounts for the difference in the opinions of the attesting physician and the auditing cardiologist, such argument is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the opinions of claimant's cardiologists cannot be medically reasonable where the auditing cardiologist and Technical Advisor both concluded that Ms. Boggess had a rheumatic mitral valve. To conclude otherwise

would allow a claimant with a rheumatic mitral valve to receive Matrix A-1 benefits rather than Matrix B-1 benefits. This result would render meaningless the standards established in the Settlement Agreement.[14]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she did not have a rheumatic mitral valve. Therefore, we will affirm the Trust's denial of this claim for Matrix A-1, Level III benefits.

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14. In any event, the Technical Advisor specifically took into account the concept of inter-reader variability, as reflected in his statement, "An echocardiographer could not reasonably conclude that rheumatic involvement of the mitral valve was not present on this study even taking into account inter-reader variability."